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| 10/533,054 | 04/27/2006 | Pieter Johan Peeters | PRD-2009-USPCT1 | 9048 |

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| EXAMINER |
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KAPUSHOC, STEPHEN THOMAS

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| ART UNIT | PAPER NUMBER |
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1634

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05/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/533,054 | Applicant(s) PEETERS ET AL. | |
| | Examiner STEPHEN KAPUSHOC | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-32 is/are pending in the application.
- 4a) Of the above claim(s) 6-14 and 16-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/27/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-14 and 16-32 are pending.
Claim 15 is cancelled.
Claims 6-14 and 16-32 are withdrawn from examination as detailed below.
Claims 1-5 are examined on the merits.

Election/Restrictions

1. Applicant's election without traverse of the invention of group 1 (claims drawn to diagnosis of CRH induced expression profile comprising gene transcription analysis), and the election of the single particular sequence of SEQ ID NO: 19, in the reply filed on 04/27/2009 is acknowledged.

Claims 6-14 and 16-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/27/2009.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement; see pages 51-53 of the specification. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, or have been included in an IDS, they have not been considered.

Objection to the Specification – Sequence Compliance

3. This application (10/533,054) contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 at least for the reason(s) set forth below:

37 CFR 1.821(d) requires that :

Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

In the case of the instant Application, the sequences of primers are listed in the table on pages 44-45, however each recitation of a sequence is not accompanied by a sequence identifier. It is noted that the amendment to the specification of 12/19/2005 provides that the table discloses 'SEQ ID NOS 42-65, respectively in order of appearance'. However this recitation in the paragraph preceding the table does not identify the sequences where they appear.

In the instant case the table should be amended such that each sequence recitation is followed by the appropriate SEQ ID NO:. For example:

5'-CATCTTGGCCTCACTGTCCAC-3' (SEQ ID NO: 42).

In order for any response to this Office Action to be considered fully responsive, the response must put the application in compliance with the sequence rules.

Claim Objections

4. Claim 1 is objected to because of the following informalities:

Claim 1 recites the abbreviation 'CRH', where at the first instance of the abbreviation in the claims, the abbreviation should be accompanied by the full meaning of the abbreviation. For example: 'a CRH (corticotropin releasing hormone) induced'.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

In the rejection of claims under 35 USC 102 as anticipated by the prior art, the required active process steps of the claims methods are noted. The claims require only (as recited in claim 1) obtaining a biological sample, and determining a level of gene expression of genes with the recited sequences (e.g.: SEQ ID NO: 19 as consonant with the Election, and the sequences recited in the claims). The claims do not require detecting any particular level (e.g. absolute or relative expression level) of gene expression, nor any particular correlation between a determined gene expression level and a diagnosis of a CRH induce profile. For example, the method steps of the claims (e.g. claim 1, with regard to SEQ ID NO: 19 as consonant with the election) encompass a method wherein it is determined that there is no expression of a gene comprising SEQ ID NO: 19 in a biological sample.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamazaki et al (available online 03/11/2002).

Yamazaki et al teaches the analysis of gene expression in mouse tissue samples by determining gene expression using the Affymetrix Murine Genomic U74Av2 GeneChip. The analysis GeneChip of the cited prior art is the same microarray as used in the example of the instant specification (p.41 Ins.26-30). Thus the analysis of the cited prior art determines the level of gene expression of genes with the required sequence elements as recited in the claims as evidenced by the instant specification (i.e. the instant specification teaches that an analysis using the U74Av2 array determines expression of gene recited in Table 1 of the specification) as well as the Examiner's search of the probes sets contained on the U74Av2 array (available using the netaffyx search tool from www.affymetrix.com).

Relevant to claim 1-5, as discussed above, Yamazaki et al teaches methods wherein a biological sample is obtained from an individual (p.1118 - High density oligonucleotide microarray analysis; Fig 2 and 3 legends), and analysis of gene transcription by hybridization to the U74Av2 array (p.1118 - High density oligonucleotide microarray analysis; p.1118 – right col. – Results and discussion). Relevant to the requirements of the gene for which the level of gene transcription is determined, as discussed above, in the analysis of Yamazaki et al the level of transcription of a gene comprising SEQ ID NO: 19 (consonant with the election, relevant to claim 1) is determined, the level of transcription for genes having SEQ ID NO: 1-9, 11, 13, 15, 17, 19, 21, 23, 25-32, 34, 36, 38 and 40 is determined (relevant to claim 3), and gene

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transcription is assessed using a probe that binds to a polynucleotide comprising SEQ ID NO: 19 (consonant with the election, relevant to claim 4). Relevant to claim 2, Yamazaki et al teaches analysis of tissue samples (Fig 2 and 3 legends). Relevant to claim 5, Yamazaki et al teaches methods of analysis using microarray technology (p.1118 - High density oligonucleotide microarray analysis).

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Stephen Kapushoc/
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